Complete Summary

GUIDELINE TITLE

UK national guidelines for HIV testing 2008.

BIBLIOGRAPHIC SOURCE(S)

UK national guidelines for HIV testing 2008. London (UK): British HIV Association, British Association for Sexual Health and HIV, British Infection Society; 2008 Sep. 23 p. [42 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Rogstad KE, Palfreeman A, Rooney G, Hart G, Lowbury R, Mortimer P, Carter P, Jarrett S, Stewart E, Summerside J. United Kingdom national guidelines on HIV testing. London (UK): Clinical Effectiveness Group, British Association for Sexual Health and HIV; 2006. 22 p. [31 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Human immunodeficiency virus (HIV)Â infection

GUIDELINE CATEGORY

Counseling
Diagnosis
Evaluation
Prevention

Risk Assessment
Screening

CLINICAL SPECIALTY

Emergency Medicine
Family Practice
Infectious Diseases
Internal Medicine
Obstetrics and Gynecology
Pediatrics
Urology

INTENDED USERS

Advanced Practice Nurses
Clinical Laboratory Personnel
Nurses
Physicians

GUIDELINE OBJECTIVE(S)

- To facilitate an increase in human immunodeficiency virus (HIV) testing in all healthcare settings as recommended by the United Kingdom's (UK's) Chief Medical Officers and Chief Nursing Officers in order to reduce the proportion of individuals with undiagnosed HIV infection, with the aim of benefiting both individual and public health
- To provide the information needed to enable any clinician to perform an HIV test within good clinical practice and encourage 'normalisation' of HIV testing

TARGET POPULATION

- Individuals presenting with 'clinical indicator diseases' (see Table 1 and Table 2 in the original guideline document) (i.e., where human immunodeficiency virus [HIV] infection enters the differential diagnosis)
- Populations where screening is indicated on the basis of prevalence data
- All individuals presenting in the following settings: genitourinary medicine or sexual health clinics, antenatal services, termination of pregnancy services, drug dependency programmes, healthcare services for those diagnosed with tuberculosis, hepatitis B, hepatitis C and lymphoma
- Patients diagnosed with a sexually transmitted infection, sexual partners of men and women known to be HIV positive, men who have disclosed sexual contact with other men, female sexual contacts of men who have sex with men, patients reporting a history of injecting drug use, persons known to be from a country of high HIV prevalence (>1%), persons who report sexual contact abroad or in the UK with individuals from countries of high HIV prevalence
- Blood donors, dialysis patients, and organ transplant donors and recipients

INTERVENTIONS AND PRACTICES CONSIDERED

1. Human immunodeficiency virus (HIV) testing, including who can test, who should be offered a test, how often to test, and which test to use
2. Pre-test discussion
3. Post-test discussion

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of screening tests
- Incidence of human immunodeficiency virus (HIV) infection
- Number new HIV diagnoses
- Uptake of testing rates
- Antenatal testing rates
- CD4 cell count
- Onward transmission rates
- Morbidity
- Mortality rates
- Cost

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

To update the guidelines, databases were searched for systemic reviews published from January 2006 through January 31, 2008. Systemic review filters were not used; instead the following key words were used: systemic review, meta-analysis or meta analysis in title and abstract when the results were not manageable. Sources searched were National Institute for Health and Clinical Excellence (NICE), Scottish Intercollegiate Guidelines Network (SIGN), Embase, Centre for Reviews and Dissemination (CRD) (Database of Abstracts of Reviews of Effects [DARE], Health Technology Assessment [HTA], National Health Service Economic Evaluation Database [NHS EED]), Cochrane Database of Systemic Reviews, PubMed, Cumulative Index to Nursing and Allied Health Literature (CINAHL), King's Fund, Turning Research into Practice (TRIP) Database and Global Health.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The guidelines have been developed in accordance with the principles laid down by the Appraisal of Guidelines Research and Evaluation (AGREE) Collaboration http://www.agreecollaboration.org/map/.

The Guideline writing committee was formed by inviting relevant specialist societies, colleges and agencies to nominate members. Nominations were also sorted from both the human immunodeficiency virus (HIV) community through the United Kingdom (UK) HIV treatment advocates network and from the lay community through the Royal College of Physicians.

The writing committee met on four occasions to evaluate and systematically review the literature, including recent conference abstracts, assess the quality of the literature, and qualitatively synthesise the included evidence as it related to both clinical and cost effectiveness. Where no evidence was available the group relied on its expert advisors and guidance from the General Medical Council (GMC) on both "good medical practice" and "patients and doctors making decisions together." Areas of disagreement were resolved by discussion until a unanimous consensus was reached.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The organizational and cost implications of the recommended guidelines were taken into consideration in the development of the guidelines.

Modelling in the US has suggested that routine screening for human immunodeficiency virus (HIV) infection is cost effective and comparable to costs of other routinely offered screening where the prevalence of HIV exceeds 0.05 percent.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The draft guidelines were reviewed by the Department of Health Expert Advisory Committee on acquired immunodeficiency syndrome (AIDS) and then subjected to an online external public consultation via all three of the commissioning societies' websites (British HIV Association [BHIVA], British Association of Sexual Health and HIV [BASHH], British Infection Society [BIS]) for one month for invited views and comment. The list of organizations which responded is listed in the original guideline document. The writing committee assessed the responses received and based on its merits and evidence provided and modified the guideline as appropriate.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Confidentiality and Human Immunodeficiency Virus (HIV) Testing

The result of an HIV test (if positive) should be given directly by the testing clinician (or team) to the patient and not via any third party, including relatives or other clinical teams unless the patient has specifically agreed to this (*see* the section on post-test discussion in the original guideline document).

Recommendations for Testing

Who Can Test?

It should be within the competence of any doctor, midwife, nurse or trained healthcare worker to obtain consent for and conduct an HIV test.

Who Should Be Offered a Test?

Universal HIV testing is recommended in all of the following settings:

- Genitourinary medicine (GUM) or sexual health clinics
- Antenatal services
- Termination of pregnancy services
- Drug dependency programmes
- Healthcare services for those diagnosed with tuberculosis, hepatitis B, hepatitis C and lymphoma.

An HIV test should be considered in the following settings where diagnosed HIV prevalence in the local population (PCT/LA) exceeds 2 in 1000 population (see local PCT data)*:

- All men and women registering in general practice
- All general medical admissions

The introduction of universal HIV testing in these settings should be thoroughly evaluated for acceptability and feasibility and the resultant data made available to better inform the ongoing implementation of these guidelines.

HIV testing should be also routinely offered and recommended to the following patients:

- All patients presenting for healthcare where HIV, including primary HIV infection, enters the differential diagnosis (see table of indicator diseases and section on primary HIV infection)
- All patients diagnosed with a sexually transmitted infection
- All sexual partners of men and women known to be HIV positive
- All men who have disclosed sexual contact with other men
- All female sexual contacts of men who have sex with men
- All patients reporting a history of injecting drug use
- All men and women known to be from a country of high HIV prevalence (>1%**)
- All men and women who report sexual contact abroad or in the UK with individuals from countries of high HIV prevalence.*

**For an up to date list see http://www.unaids.org/en/KnowledgeCentre/HIVData/Epidemiology/latestEpiData.asp.

*Diagnosed prevalence is a good indicator of the undiagnosed prevalence in a population (ratio 2:1). All PCTs are routinely informed of the diagnosed prevalence rate by the Health Protection Agency (HPA) Survey of Prevalent HIV Diagnoses (SOPHID) data on an annual basis (further information on SOPHID data and its dissemination is available at http://www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb_C/1201767906579).

A diagnosed prevalence exceeding 2 in 1000, in those aged between 15 and 59, is a proxy for an undiagnosed prevalence exceeding 1 in 1000, the threshold at which routine testing is assumed to be cost effective based on the US data.

HIV testing should also be routinely performed in the following groups in accordance with existing Department of Health guidance:

- Blood donors
- Dialysis patients
- Organ transplant donors and recipients

How Often to Test?

Repeat testing should be provided for the following groups:

- All individuals who have tested HIV negative but where a possible exposure has occurred within the window period
- Men who have sex with men (MSM) – annually or more frequently if clinical symptoms are suggestive of seroconversion or ongoing high risk exposure
- Injecting drug users – annually or more frequently if clinical symptoms are suggestive of seroconversion (see the section on Suspected Primary HIV Infection)
- Antenatal care – women who refuse an HIV test at booking should be re-offered a test, and should they decline again a third offer of a test should be

made at 36 weeks. Women presenting to services for the first time in labour should be offered a point of care test (POCT).

A POCT test may also be considered for the infant of a woman who refuses testing antenatally.

In areas of higher seroprevalence, or where there are other risk factors, women who are HIV negative at booking may be offered a routine second test at 34–36 weeks' gestation as recommended in the British HIV Association (BHIVA) pregnancy guidelines.

Which Test to Use?

There are two methods in routine practice for testing for HIV, involving either venipuncture and a screening assay, in which blood is sent to a laboratory for testing, or a rapid point of care test (POCT).

Blood Tests

The recommended first-line assay is one which tests for HIV antibody AND p24 antigen simultaneously. These are termed fourth generation assays, and have the advantage of reducing the time between infection and testing HIV positive to one month which is one to two weeks earlier than with sensitive third generation (antibody only detection) assays. It is reasonable to expect universal provision of these assays, although they are not offered by all primary screening laboratories.

HIV RNA quantitative assays (viral load tests) are not recommended as screening assays because of the possibility of false positive results, and also only marginal advantage over fourth generation assays for detecting primary infection.

Confirmatory Assays

Laboratories undertaking screening tests should be able to confirm antibody and antigen/RNA. There is a requirement for three independent assays, able to distinguish HIV-1 from HIV-2. These tests could be provided within the primary testing laboratory or by a referral laboratory. All new HIV diagnoses should be made following appropriate confirmatory assays and testing a second sample.

Testing including confirmation should follow the standards laid out by the Health Protection Agency.

<u>Point of Care Testing (POCT)</u>

Point of care tests offer the advantage of a result from either a fingerprick or mouth swab sample within minutes. They have advantages of ease of use when venipuncture is not possible, e.g., outside conventional healthcare settings and where a delay in obtaining a result is a disadvantage, but these must be weighed against the disadvantages of a test which has reduced specificity and reduced sensitivity versus current fourth generation laboratory tests. Due to the low specificity of POCT and therefore the resulting poor positive predictive value all positive results must be confirmed by serological tests as there will be false

positives, particularly in lower prevalence environments. Only CE-marked POCT kits should be used and a nominated accredited pathology laboratory should assist with governance issues and quality assurance of the testing process.

POCT is therefore recommended in the following contexts (see British Association of Sexual Health and HIV [BASHH] Point of Care Testing Guidance):

- Clinical settings where a rapid turnaround of testing results is desirable
- Community testing sites
- Urgent source testing in cases of exposure incidents
- Circumstances in which venipuncture is refused

General Laboratory Issues

All laboratories undertaking any diagnostic HIV services should be able to demonstrate satisfactory external quality control data for the tests undertaken, and should have full accreditation status [such as clinical pathology accreditation (CPA)].

All laboratories must have satisfactory HIV diagnosis confirmatory assay systems available to allow timely definitive diagnoses. This may involve referring samples to specialist virology laboratories, if appropriate, or even national reference laboratories.

All acute healthcare settings should expect to have access to an urgent HIV screening assay result ideally within eight hours, and definitely within 24 hours, to provide optimal support for exposure incidents.

Routine opt-out test results should be expected to be available within 72 hours.

Pre-Test Discussion

The primary purpose of pre-test discussion is to establish informed consent for HIV testing. Lengthy pre-test HIV counselling is not a requirement, unless a patient requests or needs this. The essential elements that the pre-test discussion should cover are:

- The benefits of testing to the individual
- Details of how the result will be given

This approach has been successful in genitourinary (GU) and antenatal clinics and is generally acceptable.

For some patients, raising the issue of HIV testing in other scenarios might require more explanation as to why the doctor or nurse is recommending this, for example when a patient presents with a condition which is more common in HIV infection.

As with any other medical investigation, the discussion should address any other issues which may be raised by the patient as it is important that patients are

given the opportunity to make a decision with adequate information about the test and the virus.

If a patient refuses a test, the reasons why they have made that choice should be explored to ensure that these are not due to incorrect beliefs about the virus or the consequences of testing. If implications for either insurance or criminal prosecution for transmission are raised by the individual as reasons for not testing, these should be further explored and any factual inaccuracies corrected (*see* Appendices 6 and 7 in the original guideline document).

Some patients may need additional help to make a decision, for example, because English is not their first language. It is essential to ensure that these patients have understood what is proposed and why. It is also important to establish that the patient understands what a positive and a negative result mean in terms of infection with HIV as some patients could interpret 'positive' as good news.

Children and young people, and those with learning difficulties or mental health problems, may need additional support and time to understand what is proposed and to make a decision (*see* Appendices 3 and 4 in the original guideline document).

As with any other investigation the offer of an HIV test should be documented in the patient's case record together with any relevant discussion. If the patient refuses a test the reasons for this should be documented. Usually, written consent is unnecessary and may discourage HIV testing by exceptionalising it.

This advice is consistent with the General Medical Council (GMC) Guidance Consent: patients and doctors making decisions together.

Post-Test Discussion

As with any medical investigation it is essential that clear procedures are established as to how the patient will receive the result, with particular attention paid to the means by which a positive result will be delivered.

Arrangements for communicating the results should always be discussed and agreed with the patient at the time of testing, particularly if the test is being performed in an outpatient or emergency care setting. Face-to-face provision of HIV test results is strongly encouraged for:

- Ward-based patients
- Patients more likely to have an HIV-positive result
- Those with mental health issues or risk of suicide
- Those for whom English is a second language
- Young people under 16 years
- Those who may be highly anxious or vulnerable

Post-Test Discussion for Individuals Who Test HIV Negative

It is considered good practice to offer health promotion screening for sexually transmitted infections and advice around risk reduction or behaviour change

including discussion relating to post-exposure prophylaxis (PEP) to those individuals at higher risk of repeat exposure to HIV infection. This is best achieved by onward referral to GUM or HIV services or voluntary sector agencies.

The need for a repeat HIV test if still within the window period after a specific exposure should be discussed. Although fourth generation tests shorten the time from exposure to seroconversion a repeat test at three months is still recommended to definitively exclude HIV infection.

Occasionally HIV results are reported as reactive or equivocal. These patients may be seroconverting (see the section on Suspected Primary HIV Infection) and management of re-testing may be complex and so such individuals should be promptly referred to specialist care.

Post-Test Discussion for Individuals Who Test HIV Positive

As is good clinical practice for any situation where bad news is being conveyed, the result should be given face to face in a confidential environment and in a clear and direct manner. If a patient's first language is not English, consideration should be given to utilisation of an appropriate confidential translation service.

If a positive result is being given by a non-GUM/HIV specialist, it is essential, prior to giving the result, to have clarified knowledge of local specialist services and have established a clear pathway for onward referral.

It is recommended that any individual testing HIV positive for the first time is seen by a specialist (HIV clinician, specialist nurse or sexual health advisor or voluntary sector counsellor) at the earliest possible opportunity, preferably within 48 hours and certainly within two weeks of receiving the result.

More detailed post-test discussion (including assessment of disease stage, consideration of treatment, and partner notification) will be performed by the GUM/HIV specialist team.

Non-Attendance for Positive Results

It is recommended to have an agreed recall process following failure of a patient to return for a positive result as with any other medical condition.

As with all other medical investigations it is the responsibility of the healthcare professional requesting the test to ensure that all results of investigations requested are received and acted upon where necessary.

If there is no means of contacting the patient or if attempts are unsuccessful, it is recommended that advice be sought from the local GUM/HIV team who are likely to have experience and resources to deal with this issue.

Suspected Primary HIV Infection

Primary HIV infection (PHI) or seroconversion illness occurs in approximately 80 percent of individuals, typically two-to-four weeks after infection. It is well

recognised that this represents a unique opportunity to prevent onward transmission as an individual is considerably more infectious at this stage. Furthermore this may be the only clinical opportunity to detect HIV before advanced immunosuppression many years later.

It is known that the features of PHI are non-specific, that individuals usually do present to medical services (primary or emergency care), but frequently the diagnosis is missed or not suspected.

The typical symptoms include a combination of any of:

- Fever
- Rash (maculopapular)
- Myalgia
- Pharyngitis
- Headache/aseptic meningitis

These resolve spontaneously within two-to-three weeks and therefore if PHI is suspected, this needs to be investigated at the time of presentation and not deferred.

It is recommended that consideration be given to HIV testing in any person with these symptoms perceived to be at risk of infection. It is acknowledged that in some non-GUM settings details of an individual's sexual risk may be difficult to ascertain, but a low threshold for offering a test should remain.

Although with fourth generation tests infection can be detected much earlier than previously (see the section on which test to use), in very recent infection – when patients may be most symptomatic – the test may be negative. In this scenario, if PHI is suspected, either urgent referral to specialist services (GU clinic or HIV service) or a repeat test in seven days is recommended. HIV viral load testing can be used in this clinical setting, but it is recommended that this is only performed with specialist input.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate use of human immunodeficiency virus (HIV) testing

- Timely diagnosis of HIV
- Reduction of the number of undiagnosed HIV infections
- Decreased HIV-related morbidity and mortality
- Reduction in onward transmission

POTENTIAL HARMS

Potential disadvantages to community testing include the limitations of the current point of care testing (POCT) technologies, such that very recent infection may be missed, and the higher rates of 'false positive' results compared to conventional laboratory-based testing. It is essential that anyone performing HIV testing in a non-healthcare setting has adequate governance arrangements including quality assurance.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

UK national guidelines for HIV testing 2008. London (UK): British HIV Association, British Association for Sexual Health and HIV, British Infection Society; 2008 Sep. 23 p. [42 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 (revised 2008 Sep)

GUIDELINE DEVELOPER(S)

British Association for Sexual Health and HIV - Medical Specialty Society
British HIV Association - Disease Specific Society
British Infection Society - Professional Association

SOURCE(S) OF FUNDING

No specific or external funding was sought or provided in the development of this guideline.

GUIDELINE COMMITTEE

Clinical Effectiveness Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Writing Committee: Adrian Palfreeman, British Association for Sexual Health and HIV (BASHH); Martin Fisher, British HIV Association (BHIVA); Ed Ong, British Infection Society (BIS); James Wardrope, College of Emergency Medicine; Ewen Stewart, Royal College of General Practitioners; Enrique Castro-Sanchez, Royal College of Nursing; Tim Peto, Royal College of Physicians; Karen Rogstad, Royal College of Physicians; Karen Rogstad, Royal College of Paediatrics and Child Heath; Julian Sheather, British Medical Association; Brian Gazzard, Department of Health Expert Advisory Group on AIDS; Deenan Pillay, Department of Health Expert Advisory Group on AIDS; Jane O'Brien, General Medical Council; Valerie Delpech, Health Protection Agency; Ruth Lowbury, Medical Foundation for AIDS and Sexual Health (MedFASH); Russell Fleet, Medical Foundation for AIDS and Sexual Health (MedFASH); Yusef Azad, National AIDS Trust; Hermione Lyall, Children's HIV Association (CHIVA); James Hardie, Society of Sexual Health Advisors; Godwin Adegbite, UK CAB; Guy Rooney, BASHH Clinical Effectiveness Group; Richard Whitehead, Lay representative

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Rogstad KE, Palfreeman A, Rooney G, Hart G, Lowbury R, Mortimer P, Carter P, Jarrett S, Stewart E, Summerside J. United Kingdom national guidelines on HIV testing. London (UK): Clinical Effectiveness Group, British Association for Sexual Health and HIV; 2006. 22 p. [31 references]

GUIDELINE AVAILABILITY

Electronic copies: Available from the British Association for Sexual Health and HIV Web site.

AVAILABILITY OF COMPANION DOCUMENTS

Auditable standards are provided in Appendix 9 of the original guideline document.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on June 8, 2007. This NGC summary was updated by ECRI Institute on August 21, 2009.

COPYRIGHT STATEMENT

Date Modified: 11/23/2009